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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit:	3773
Confirmation No.:	5422
Application No.:	10/758,372
Invention:	SOFT TISSUE LOCKING DEVICE
Inventor:	Herbert E. Schwartz et al.
Filed:	January 15, 2004
Attorney Docket:	26502-73682
Examiner:	Woo, Julian W.

ELECTRONICALLY SUBMITTED:

August 24, 2010

REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants submit electronically this Reply Brief in support of the appeal from the Primary Examiner's rejection of claims 1-4 and 6-17 set forth in the Final Office Action dated October 13, 2009 (hereinafter "Final Office Action") and the Examiner's Answer dated June 24, 2010. Appellants hereby authorize the Director to charge any additional fees or credit any overpayments to Deposit Account No. 10-0435 with reference to our file number 26502-73682.

ARGUMENT IN REPLY

Appellants submit this Reply Brief in response to the Examiner's Answer dated June 24, 2010. In this Reply Brief, Appellants have specifically addressed certain points raised in the Examiner's Answer concerning the two grounds of rejection.

I. REPLY REGARDING THE FIRST GROUND OF REJECTION.

Appellants maintain that claims 1-4 and 6-9 are not anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,010,525 filed by Bonutti (hereinafter Bonutti).

A. Claims 1, 4, 6, and 9.

On page 5 of the Examiner's Answer, the Examiner asserted that

> *Bonutti's first anchor (element 540) is indeed capable of being seated or positioned below soft tissue, if, for example, the orientation of the soft tissue, as shown in figure 26, is turned upside down, such that first anchor 540 is deemed to be "below" the first surface of soft tissue.* Bonutti's recitation of the anchor being "pressed against an upper surface 98 of body tissue" is only referring to an instance where the orientation of the body tissue as shown in figure 26 results in the suture retainer being above the first surface of tissue. *Certainly, a patient and his or her soft tissue may be oriented in various positions, and Bonutti's first anchor is configured to be oriented and fastened in place according to the position of the soft tissue – a position that may be deemed "below the first surface of tissue."*
>
> . . . Bonutti's anchors (540 and 602), like the inventive device, are shown, in figure 26, to be on opposite sides of soft tissue – tissue that may be within a patient's body or is subcutaneous, where one of the sides of the tissue may be deemed "below [a] first surface of tissue."

(emphasis added). Respectfully, the Examiner has continued to misapply the broadest reasonable interpretation standard. While "a patient and his or her soft tissue may be oriented in various positions," Bonutti's suture retainer 540 would still be *positioned on* the surface of any soft tissue engaged by the retainer 540, regardless of the orientation of the patient. The suture retainer 540 therefore does not fulfill the requirement of "being shaped to seat below the first surface of the soft tissue" as required by the claims.

As Appellants argued on page 9 of the Appeal Brief, the phrase "shaped to seat below the first surface of the soft tissue" clearly indicates a *subcutaneous* position relative to the first

surface of the soft tissue. Nothing in Appellants' specification or within the common understanding of one skilled in the art would lead a person of ordinary skill to find that Bonutti's structure, which is shaped to be *seated on* the first surface (i.e., the outer surface) and *in contact with the largest possible area of* the outer surface, is a structure shaped *to be positioned subcutaneously or below that outer surface* as required by the claims. Indeed, when the suture retainer 540 is engaged with the outer surface of soft tissue, Bonutti's suture retainer 540 is *positioned on (and not below) that outer surface* of soft tissue.

In response to our arguments, the Examiner included a new interpretation of Bonutti on page 5 of the Examiner's Answer, stating Bonutti anticipated the claimed invention because

> Also like the inventive device, Bonutti applies tension to a suture to pull the anchors together and sandwich soft tissue therebetween. *This tensioning would inherently result in at least the partial burial or embedding of an anchor within soft body tissue. This embedding of an anchor in tissue may also be deemed a seating of the anchor "below [a] first surface of tissue."*

(emphasis added). Appellants respectfully traverse the Examiner's assertion, which is effectively nothing more than unsupported speculation. Indeed, the Examiner provides no citation to support his assertion, and, in fact, Bonutti does not expressly teach that the tensioning of the suture would result in "partial burial or embedding of" the suture retainer 540 in the outer surface of the soft tissue.

While the Examiner concludes that tensioning of the suture would cause the suture retainer 540 to partially bury or embed in the soft tissue, the Examiner has not provided the analysis or evidence necessary to support this inherency argument. To establish inherency, the Examiner is required to provide extrinsic evidence that makes "clear that the missing descriptive matter is *necessarily* present." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)). Despite this requirement, the Examiner has simply concluded that the "tensioning would inherently result in at least the partial burial or embedding of an anchor within soft body tissue" without providing the analysis to show that such "partial burial or embedding of" the suture retainer 540 will *necessarily* result from tensioning the suture. Without that evidence or analysis, the Examiner cannot establish that Bonutti inherently discloses the missing elements of the claims.

Appellants therefore maintain that the Examiner has not shown that Bonutti anticipates claims 1, 4, 6, and 9. For that reason, Appellants respectfully ask the Board to reverse the rejection of claims 1, 4, 6, and 9 under Section 102(e).

B. Claims 2 and 7.

On page 6 of the Examiner's Answer, the Examiner asserted that

> Bonutti discloses in several places (e.g., figure 1, and col. 3, lines 60-67) a device applicable to "layers" of "body tissue" or "soft body tissue." *Meniscus comprises layers of body tissue or soft body tissue*. And since Bonutti is applicable to soft body tissue, even layered body tissue, one of ordinary skill in the art may infer that Bonutti is capable of use with meniscus.

(emphasis added). While meniscus does include "layers of body tissue or soft body tissue" meniscus is generally understood to also include "a fibrous cartilage within a joint especially of the knee." *Merriam-Webster Collegiate Dictionary* (11th ed.). Thus, the mere fact that Bonutti's devices are applicable to soft body tissue does not necessarily imply that Bonutti is capable of use with meniscus. As such, the Examiner's assertion does not explain how the suture retainer 540 is *necessarily* capable of being used with meniscus.

Additionally, it simply remains unclear from Bonutti's disclosure whether or not the suture retainer 540 would interfere with joint articulation; thus, it is unclear for that reason as well whether Bonutti's device is suitable for use with meniscus. As shown in FIG. 26 of Bonutti, the suture retainer 540 appears to extend or protrude some distance away from the surface of the soft tissue. Perhaps, as the rejection suggests, Bonutti's device *might* be used with meniscus; yet given the fact that some protruding anchors interfere with joint articulation, it is equally possible that Bonutti's device *might not* be used with meniscus. Based on Bonutti's disclosure alone, it is impossible to say that Bonutti's device is necessarily capable of being used with meniscus. The rejection set forth in the Final Office Action and the Examiner's additional statements in the Examiner's Answer simply do not establish that Bonutti inherently discloses a first anchor capable of being used with meniscus as required by the claims.

Appellants therefore maintain that the Examiner has not shown that Bonutti anticipates claims 2 and 7. Appellants respectfully ask the Board to reverse the rejection of claims 2 and 7 under Section 102(e).

C. Claims 3 and 8.

On pages 6 and 7 of the Examiner's Answer, the Examiner asserted that

> Appellant has not specified, in the claims, which joint is being articulated when a device is seated in tissue, nor has the Appellant specified the size and configuration of the soft tissue or meniscus to be repaired. *Bonutti's device is applicable to body tissue away from several body joints, so clearly, Bonutti's device is capable of being seated without affecting, say, a distant joint.*

(emphasis added). Appellants respectfully traverse the Examiner's assertion that Bonutti's device, if shaped to be positioned on a body tissue other than a joint, somehow includes all of the limitations of claims 3 and 8. Claims 3 and 8 depend from claims 2 and 7, which specify that the soft tissue engaged by the anchor "is a meniscus." As such, the joint being referenced in claims 3 and 8 is the **same** joint possessing that meniscus. A person of ordinary skill would therefore understand that claims 3 and 8 require the proper seating of the device to close the defect without interfering with articulation of the joint where the anchor is positioned – the articulation of some "distant joint" located elsewhere in the body is irrelevant to the analysis of the claims.

The Examiner further asserted that

> Bonutti indeed discloses the capability of use with soft tissue, which may include meniscus by inference. Soft tissue or meniscus can come in various sizes and shapes. Moreover, anchors can obviously be chosen or sized, shaped, and positioned according to the sizes and shapes of tissue being treated and according to the location of a defect. Thus, depending on the meniscal or defect configuration and location, Bonutti's device may be chosen and seated in tissue without affecting joint articulation.

Examiner's Answer, at pages 6-7. Respectfully, the Examiner is offering what is effectively mere speculation regarding the properties of Bonutti's device. As discussed above in regard to claims 2 and 7, the mere fact that Bonutti's devices are applicable to soft body tissue does not *necessarily* imply that Bonutti is capable of use with the meniscus of a joint. Bonutti does not disclose using the suture retainer 540 in connection with a knee joint and contains no discussion of joint articulation. Nothing in the rejection set forth in the Final Office Action or the Examiner's additional statements included in the Examiner's Answer establishes that Bonutti's devices are inherently capable of properly seating such that defect is closed without interfering with joint articulation as required by the claims.

Appellants therefore maintain that the Examiner has not shown that Bonutti anticipates claims 3 and 8. Appellants respectfully ask the Board to reverse the rejection of claims 3 and 8 under Section 102(e).

II. REPLY REGARDING THE SECOND GROUND OF REJECTION.

Appellants maintain that the claims 10-17 are not unpatentable under 35 U.S.C. § 103(a) over Bonutti in view of U.S. Patent No. 5,391,173 issued to Wilk (hereinafter Wilk). Appellants incorporate the analysis and arguments set forth above in Section I into this section.

A. Claims 10 and 13-17.

On page 7 of the of the Examiner's Answer, the Examiner asserted that

> First, as set forth above, Bonutti's device is capable of being seated below a surface of soft tissue. Wilk provides a teaching of a suture anchor (8) with a frustoconical end, where the broad, flat circular bottom side of the anchor is engaged with soft tissue (just like Bonutti's device). Thus, as set forth in the rejection, Bonutti is modified to a frustoconical shape as taught by Wilk, *where Bonutti and Wilk teach the large, bottom sides of their anchors, rather than narrow sides, being engaged with tissue, where the anchors are configured to be "below" a surface of tissue (as defined above) or partially buried in soft tissue.*

(emphasis added). Appellants note that the Examiner has admitted that the Bonutti device, as modified by the rejection, would have a "frustoconical end" that is *never* in contact with the surface of the soft tissue. Such a device fails to arrive at or render obvious the claimed invention. Indeed, in light of the Examiner's statements, the rejection is rendered almost moot.

The claims require "a first anchor for engaging a first surface of the soft tissue" that includes "a frustoconical end shaped to bury into and seat below the first surface of the soft tissue." In other words, the claims require the frustoconical end be configured to *bury into and seat below* the *same* surface engaged by the first anchor. "To bury into" the first surface of the soft tissue, the frustoconical end must make *at least some contact with the first surface*, yet the Examiner admits that the frustoconical end" of the modified Bonutti device would *never* be in contact with the surface of the soft tissue. If the frustoconical end of the modified device is never in contact with the surface of the soft tissue, it is simply illogical to suggest that the end is

somehow shaped to bury into and seat below the surface of the soft tissue. In at least that regard, the rejection of claims 10 and 13-17 is flawed and should be reversed.

As discussed above in regard to claims 1, 4, 6, and 9, nothing in Appellants' specification or anything within the common understanding of one skilled in the art would lead a person of ordinary skill to find that Bonutti's structure, which is shaped to be *seated on* the first surface and *in contact with the largest possible area of* the first surface, is a structure shaped *to be positioned subcutaneously or below that first surface* as required by the claims. While "a patient and his or her soft tissue may be oriented in various positions," Bonutti's suture retainer 540 would still be *positioned on* the surface of any soft tissue engaged by the retainer 540, regardless of the orientation of the patient. The suture retainer 540 therefore does not fulfill the requirement of "being shaped to bury into and seat below the first surface of the soft tissue" as required by the claims.

Appellants therefore maintain that the rejection is based on a flawed interpretation of the "shaped to bury into and seat below the first surface of the soft tissue." For that reason, the rejection has failed to establish that claims 10 and 13-17 are rendered *prima facie* obvious by the combination of Wilk and Bonutti. Appellants respectfully urge the Board to reverse the rejection of those claims.

B. Claim 11.

On pages 7 and 8 of the Examiner's Answer, the Examiner asserted that "Bonutti in view of Wilk is capable of use with meniscus" and advanced the same arguments with respect to claim 11 that were made with respect to claims 2 and 7. As highlighted in Section I.B above, the mere fact that Bonutti's devices are applicable to soft body tissue does not automatically imply that Bonutti is capable of use with meniscus. As such, the Examiner's assertion does not explain how the combination of Bonutti and Wilk results in a device that is *necessarily* capable of being used with meniscus.

Based on disclosures of Bonutti and Wilk, it is impossible to say that the resulting device is *necessarily* capable of being used with meniscus, and the Examiner has simply not set forth the required extrinsic evidence or reasoning that makes "clear that the missing descriptive matter is necessarily present." *See In re Robertson*, 169 F.3d 743, 745, 49 USPQ 2d 1949, 1950-51

(Fed. Cir. 1999) (citations omitted). Appellants therefore submit that the Examiner has failed to show that proposed combination expressly or inherently arrives at the invention of claim 11. The Examiner has failed to put forth the required factual basis for the rejection; as such, the Examiner has failed to establish that claim 11 is rendered *prima facie* obvious by the combination of Wilk and Bonutti. Appellants respectfully urge the Board to reverse the rejection of that claim.

C. Claims 12.

On page 8 of the Examiner's Answer, the Examiner asserted that "Bonutti in view of Wilk is capable of seating in tissue without interfering with joint articulation" and advanced the same arguments with respect to claim 11 that were made with respect to claims 3 and 8. Contrary to the assertions made by the Examiner, the claim language requires the proper seating of the device to close the defect without interfering with articulation of the joint where the anchor is positioned – the articulation of some "distant joint" located elsewhere in the body is irrelevant to the analysis of the claim.

Neither Bonutti nor Wilk expressly disclose a device used in connection with a knee joint and neither reference contains a discussion of joint articulation. Nor has the Examiner provided the analysis or evidence necessary to show that the device resulting from the combination of Bonutti and Wilk is inherently capable of properly seating such that the defect is closed without interfering with joint articulation. As discussed in Sections I.A and I.B, the mere fact that Bonutti's devices are applicable to soft body tissue does not automatically imply that Bonutti is capable of use with the meniscus of a joint. For that reason, the rejection set forth in the Final Office Action and the Examiner's additional statements in the Examiner's Answer do not establish that the device resulting from the combination of Bonutti and Wilk would be inherently capable of properly seating such that defect is closed without interfering with joint articulation as required by the claims. Appellants therefore submit that the Examiner has failed to show that proposed combination expressly or inherently arrives at the invention of claim 12. The Examiner has failed to put forth the required factual basis for the rejection; as such, the Examiner has failed to establish that claim 12 is rendered *prima facie* obvious by the combination of Wilk and Bonutti. Appellants respectfully urge the Board to reverse the rejection of that claim.

III. SUMMARY CONCLUSIONS

In view of the arguments presented above, Appellants submit that the two grounds of rejection are erroneous. On that basis, Appellants respectfully ask the Board to reverse the rejection of claims 1-4 and 6-17.

Respectfully submitted,

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